

AMENDMENTS TO THE DRAWINGS

The attached sheet(s) of drawings includes changes to Sheets 1 & 2, and the addition of Sheet 3. Specifically, the numbering of the Sheet on Sheets 1 & 2 has been modified to indicate there are now 3 sheets of drawings instead of 2. Additionally, Sheet 3, **FIG. 6**, has been added in accordance with the suggestion of the Examiner. **FIG. 6** is an exact replication of **FIG. 1**, with the exception of the extension of the plurality of furcated branches to a distance of at least half of the length of the shaft of the bone screw, in accordance with originally filed claim 4 describing such a configuration.

Attachment: Replacement Sheets 1 & 2
New Sheet 3

REMARKS

Upon entry of this paper, claims 2, 7, 12, and 17 have been amended, no claims have been canceled, and no claims have been added as new claims. Thus, claims 1-20 are presently pending in this application. No new matter has been added.

Drawings

The drawings have been amended in accordance with the Examiner's recommendations to show the claimed feature of the furcated means/branches extending for at least half the length of the shaft of the bone screw. Newly added **FIG. 6** is an exact replication of **FIG. 1**, with the exception of the extension of the plurality of furcated branches to a distance of at least half of the length of the shaft of the bone screw. Such configuration was clearly described in both claim 4 and in the Summary section at the top of page 3 of the Specification. One of ordinary skill in the art reviewing the Specification and figures could have readily appreciated the configuration depicted in **FIG. 6** prior to the configuration being specifically illustrated in **FIG. 6** because of the more than sufficient textual description. However, in an effort to add additional clarifying support to claim 4, **FIG. 6** is provided in the present amendment. Accordingly, the addition of **FIG. 6** cannot be considered new matter.

Withdrawal of the drawing objections is respectfully requested in view of the addition of **FIG. 6** herewith.

Specification

The disclosure was objected to because of informalities on page 7 related to a typographical error indicating reference number "23" when reference number "24" should have been indicated. The Specification has been amended to correct this informality. As such, withdrawal of this objection is respectfully requested.

Claim Objections

Claims 7 and 17 were objected to because of a typographical error mistakenly dropping the term “bore” from the claims. Claims 7 and 17 have been amended to include the term “bore”, properly indicating a “driver bore” as described in the originally filed Specification at page 5, line 24. Accordingly, no new matter has been added with this amendment. Withdrawal of this objection is respectfully requested.

Claim Rejections 35 USC § 112

Claims 2 and 12 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 12 have been amended to indicate “an opening” at a hole, rather than “the opening” at a hole, thus providing the required antecedent basis. Additionally, claim 12 has been amended to clarify that the “radially outwardly configuration” means that the furcated means can compress from a circumferential diameter “when extended radially outwardly”, which was clearly intended in the claim as originally filed. Accordingly, no new matter has been added with these amendments. This amendment is provided merely to clarify, not modify, the original scope of the claim as filed.

Additionally, claim 12 has been amended to remove the term “relatively” and add the term “circumferential”. The Examiner objected to the use of the term “relatively” as being indefinite. However, Applicant submits that the term properly modified the phrase “smaller screw diameter” as being smaller relative to the “circumferential screw diameter” that appears earlier in the same clause of the claim. Therefore, the term “relatively” was characterizing what the “smaller” was relative to when interpreting the claim. However, in an effort to further prosecution, Applicant has re-worded the claim to indicate a starting “circumferential screw diameter” that compresses to a “smaller circumferential screw diameter” in accordance with the original interpretation and breadth of the original claim 12 as filed.

As such, Applicant submits that all 35 U.S.C. 112, second paragraph issues are addressed by the amendments provided herein. Reconsideration and withdrawal of these rejections is requested.

Claim Rejections 35 USC § 102

Claims 1-9 and 11-19 were rejected under 35 U.S.C. 102(b) as being anticipated by Enayati (U.S. Patent No. 6,290,701). Applicant respectfully traverses this rejection in view of the following remarks.

Enayati fails to anticipate all elements of claims 1-9 and 11-19, and specifically fails to anticipate all elements of independent claims 1 and 11. Enayati fails to disclose a “furcated bone screw . . .” (see claims 1 and 11), the term “screw” being located in the preamble and throughout the body of claim 1. It should be noted that the term “screw” is not a functional or intended use statement. Instead, the term “screw” incorporates structural limitations as relate generally to the category of fastener identified as a screw.

Contrary to a screw, Enayati is directed to a “rivet”. There are various interpretations that can be made with regard to the differences between a screw and a rivet when analyzing equivalents. However, in the context of the present claimed invention, one difference that is notable is that the screw configuration does not require the extra component of an “expansion pin 150” to actually expand the legs of the rivet outwardly. In fact, Enayati specifically distinguishes the “rivet” approach from the “screw” approach at col. 1, line 61 to col. 2, line 3, where it states, “[t]o overcome the *disadvantages of the screw* and staple types of bone fasteners, expandable rivets, both bioabsorbable and metallic, have been developed. . . . Such rivets, which are either bioabsorbable or metallic, have the advantage that they may be inserted into an untapped hole, thereafter to be expanded, thereby reducing the time required for implantation of the rivets.”

As such, Enayati fails to anticipate the pending claims because Enayati discloses a rivet, not a screw.

Additionally, Enayati fails to disclose “a *screw thread* circumnavigating the shaft” (*see* claims 1 and 11). The Office Action indicates that FIG. 6, referenced item #19, discloses a screw thread. However, Applicant respectfully submits that all that is disclose in FIG. 6, and throughout Enayati, is an “outer surface 19” that is “modified . . . to provide a positive attachment of the rivet to the bone” (*see* col. 5, lines 18-20). There is no mention whatsoever of the surface modification being a “thread”. Those of ordinary skill in the art will appreciate that a “screw thread”, as claimed in the pending claims, indicates “a projecting helical rib of a screw” (*see* Merriam-Webster’s Collegiate Dictionary, Tenth Edition). The “outer surface 19” of Enayati is not a single helical rib. Instead, the surface is illustrated as a plurality of circular ribs that are not connected, and are not helical.

The difference between a mere surface modification and a screw thread goes to the difference in how the devices of Enayati and the present claimed invention operate. Specifically, if one were to rotate the rivet of Enayati after placing it in a bore, the rivet of Enayati would simply spin in place. If one rotates the furcated screw of the present claimed invention after placing it in a bore, the furcated bone screw will thread itself into the bore, thus screwing the furcated bone screw into the bone. Such a difference is not a mere functional limitation or intended use.

As such, Enayati fails to anticipate a screw thread circumnavigating the shaft.

Furthermore, Enayati fails to disclose a plurality of branches being “plastically deformed radially outwardly” (*see* claims 1 and 11). Plastic deformation is understood by those of ordinary skill in the art to be irreversible. In other words, once the metal has been deformed in a direction to a point of plastic deformation, removal of the deformation force will not result in the metal returning to the pre-plastic-deformation configuration. There is no indication in Enayati that removal of the pin will result in the rivet legs maintaining their outwardly expanded configuration. In fact, there is no indication of even removing the expansion force (*i.e.*, the pin) at all if the rivet is to remain anchored in the bone. The present claimed invention makes use of a “plurality of branches are plastically deformed radially outwardly” (*see* claims 1 and 11), and are temporarily elastically deformed to insert the screw in the bone, but then as the screw is screwed into the bone, return at least partially to their plastically deformed configuration without

requirement of a pin or other external expansion force. Accordingly, Enayati fails to anticipate the pending claims with regard to the element of plastic deformation.

Anticipation can only be established by a single prior art reference teaching each and every element of the claimed invention performing the identical function in the same way. Applicant respectfully submits that claimed aspects of the present invention are conspicuously absent from Enayati and thus, there can be no anticipation.

In light of the above comments, applicant respectfully submits that claims 1-9 and 11-19 of the present invention are not anticipated by, and are therefore in condition for allowance over, the cited document. Withdrawal and reconsideration of this rejection is requested.

Claim Rejections 35 USC § 103

Claims 10 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Enayati (U.S. Patent No. 6,290,701). This rejection is respectfully traversed in view of the following remarks, in which Applicant submits that Enayati fails teach or suggest all the claimed limitations.

The furcated bone screw is indicated in claims 10 and 20 to be “formed at least partially by titanium.” However, as discussed above, Enayati fails in at least several aspects to disclose all of the claimed limitations. In addition, the disclosure of a rivet in Enayati instead of a screw, the absence of a screw thread on the rivet, and the absence of any form of plastic deformation of the legs of the rivet, likewise result in a failure of Enayati to teach or suggest all of the claimed limitations of the present claimed invention.

Applicant respectfully submits that unless a *prima facie* case of unpatentability with respect to known facts is established, applicant is not obliged to proffer any evidence of nonobviousness. To establish a *prima facie* case there must be some suggestion or motivation, either in the prior art or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine multiple reference teachings. There must then be a

reasonable expectation of success. Finally, the prior art reference or references (when combined) must teach or suggest all the claimed limitations.

Applicant submits that Enayati fails to teach or suggest all the claimed limitations. Until all elements of the independent claims are met by the prior art, there can be no obviousness rejection of the claims depending therefrom. Applicant respectfully submits that Enayati fails to teach or suggest every characteristic of Applicant's claims 1 and 11, and therefore dependent claims 10 and 20. Applicant further submits that all claims of the present invention are not obvious with respect to, and are therefore allowable over, the cited document.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicant courteously solicits allowance of the claims in the form of a Notice of Allowance. Each of Applicant's claims contains characteristics that are neither disclosed nor suggested by the cited documents. For the reasons detailed herein, Applicant respectfully requests that all rejections be reconsidered and withdrawn. This application is in condition for allowance, and notice of the same is earnestly solicited. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact applicant's representative by telephone at the number indicated below.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely.

Dated: February 13, 2006

Respectfully submitted,

By 

Sean D. Detweiler

Registration No.: 42,482

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney/Agent For Applicant

Attachments